

**Remarks**

This Supplemental Amendment is filed in reply to the Office Action mailed November 2, 2004. Claims 1-24 and 39 are pending in the application. Claims 1, 5, 7, 19 and 24 have been amended, claims 2 and 6 have been canceled and claim 39 has been added in the present application. Thus, claims 1-24 and 39 are submitted for reconsideration at this time.

**A. Rejections Under 35 U.S.C. § 102**

Claims 1-8, 10-14, 17-24 stand rejected under 35 U.S.C. §102(e) as being anticipated by Michelson et al US Application Publication No. 2002/0002474. This rejection is respectfully traversed.

Claims 1, 19, and 24 each recites, inter alia, automatically, determining whether the patient prequalifies for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria, and if the patient prequalifies for any of the clinical trials, notifying the user that the patient has prequalified for at least one specific clinical trial, presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials, determining whether the user prequalifies for the at least one specific clinical trial based on the user's response to the targeted questions, and storing the responses to the targeted questions. The critical reference date of the Michelson publication application with respect to these limitations is January 29, 2001, the filing date of the PCT application, since the provisional application to which the Michelson publication application claims priority does not properly support the subject matter relied upon to make the rejection in compliance with 35 U.S.C. 112, first paragraph. See MPEP 2136.03. Accordingly,

the Michelson publication is not prior art with respect to these limitations of claims 1, 19 and 24 since the critical reference date for these limitation is after the effective filing date of the present invention.

The critical reference date of the Michelson publication for claim 3, 5, 7, 9, 15, is also January 29, 2001, the filing date of the PCT application. since the provisional application to which the Michelson publication application claims priority also fails to properly support the subject matter relied upon to make the rejection in compliance with 35 U.S.C. 112, first paragraph. See MPEP 2136.03.

**B. Rejections Under 35 U.S.C. § 103**

Claim 9 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of Altman et al. US Patent No. 5,572,421 and claims 15-16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of Kraftson et al. US Patent No. 6,151,581. These rejections are respectfully traversed.

Claims 9, 15, and 16 depend from claim 1. Altman and Kraftson fail to cure the deficiencies of Michelson. Accordingly, claims 9, 15 and 16 are not taught or suggested by the combination of Michelson with Altman or Kraftson for the same reasons discussed above with respect to claim 1.

**C. Request for Interference**

The newly added claim 39 is a copy of currently pending claim 138 in US Application Publication No. 2002/0002474 ("the Michelson publication") entitled "SYSTEMS AND METHOD FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES," filed by Michelson et al. on August 8, 2001. The difference between the effective filing date of claim 138 of the Michelson publication and the present application is less than three months. The copied claim is not barred under 35 U.S.C. § 135(b)(2) since the present application was filed before

November 29, 2000. See § 4508 of Pub. L. 106-113. While the copied claim has not been allowed in the Michelson publication, there are unusual circumstances that justifies the Director of Technology Center 3600 approving Applicant's Request for Interference as discussed in accompanying NOTICE OF COPIED CLAIMS FROM PUBLICATION AND REQUEST FOR INTERFERENCE. Accordingly, an interference should be declared for the reasons stated above.

The following table sets forth the relationship between the claims of the present application and the Michelson publication and the proposed counts.

<u>Present application</u>	<u>Michelson publication</u>	<u>Proposed count</u>
39	138	A

The proposed count A is substantially identical to CLAIM 138 of the Michelson publication and the present application as shown above. The following table provides the detailed support in the present application for the newly added claim.

#### PROPOSED COUNT

39. A method for recruiting an individual to participate as a subject in a clinical study, comprising the steps of:

(a) presenting at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of one or more clinical studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and

#### SPECIFICATION SUPPORT

This application discloses a method that allows patients to be recruited for clinical trials. See Specification, pg. 5, lines 4-7.

This application discloses that the method is implemented at a web site. Id. This application discloses that a user who is interested in searching for available clinical trials can select links directing the user to a clinical trial search process where the user can register with the web

**PROPOSED COUNT**

contact information;

(b) automatically registering the individual with the database upon receipt of the registration and indicating information;

(c) after step (b), automatically determining, in accordance with the indicating information and the registration information, whether to provide the individual or caregiver with notice of a clinical study associated with said disease condition;

**SPECIFICATION SUPPORT**

site and create a patient profile. See Specification, pg. 9, line 23-pg. 10, line 7. The information in the a user's registration record includes contact information (See Specification, pg. 8, line 16; pg. 16, line 23) and a link to the patient's profile, which includes geographic location (See Specification, pg. 2 lines 25-26) and name of disease (See Specification, pg. 10, line 11).

When the user registers, the information is automatically stored in the user's registration record. See Specification, pg. 9, line 18-22. The user is also assigned a user ID number. Id. This user ID number is attached to the user's patient profile. Id.

This application discloses that after the patient profile is created a computer program process can automatically determine whether the patient prequalifies for a clinical trial associated with the named disease. See Specification, pg. 12, line 27, pg. 14, line 21. The determination is

**PROPOSED COUNT**

(d) providing the individual notice of said clinical study;

(e) presenting a screening questionnaire associated with said clinical study; and

**SPECIFICATION SUPPORT**

based on the user's selection of the clinical trial search process and the patient profile. See Specification, pg. 12, lines 15-20.

This application discloses that the user can be informed that they qualify for clinical trials. See Specification, pg. 15, lines 11-12 and 20-21.

This application discloses that after a preliminary determination of whether the patient prequalifies for any clinical trials targeted questions specific to each clinical trial for which the patient has preliminarily qualified are provided. See Specification, pg. 15, lines 11-12.

The patient is allowed to submit an application for each trial site for which he or she qualifies. See Specification, pg. 15, lines 13-25.

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**PROPOSED COUNT**

(f) storing answers submitted by the individual in the database.

**SPECIFICATION SUPPORT**

The patient's applications and medical profile are submitted online to EmergingMed.com server where they are stored in a database.

Specification, pg. 15, lines 13-25.

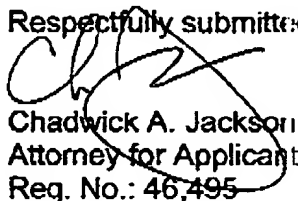
Attorney Docket No 18966 0002

U.S. Serial No 09:699,372  
Courtney HUDSON**CONCLUSION**

In view of the above amendments and remarks, Applicant respectfully requests that all objections and rejections recited in the Office Action mailed November 2, 2004 be suspended. While neither the Michelson publication nor the present application has been allowed, Applicant has demonstrated the existence of conflicting claims between the applications. Accordingly, pursuant to 37 CFR § 1.604, Applicant requests that an interference be declared between the present application and the Michelson publication. The Examiner is invited to contact the undersigned for any reason related to the advancement of this case.

Date: July 11, 2005

Respectfully submitted,

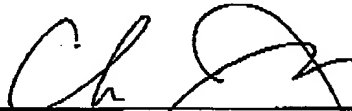
  
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Amendment